

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN

District of

NEW YORK

PAUL JOHNSON,

Plaintiff,

V.

ELI LILLY AND COMPANY

Defendants.

SUMMONS IN A CIVIL CASE

CASE NUMBER:

08 CV 0987

TO: (Name and address of Defendant)

ELI LILLY AND COMPANY
875 Avenue of the Americas
Suite 501
New York, NY 10001

YOU ARE HEREBY SUMMONED and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

FINKELSTEIN & PARTNERS, LLP
436 Robinson Avenue
Newburgh, NY 12550

an answer to the complaint which is herewith served upon you, within Twenty (20) days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

J. MICHAEL McMAHON

CLERK

JAN 30 2008

DATE

(By) DEPUTY CLERK

OAO 440 (Rev. 8/01) Summons in a Civil Action

RETURN OF SERVICE

Service of the Summons and complaint was made by me ⁽¹⁾	DATE
NAME OF SERVER (PRINT)	TITLE

Check one box below to indicate appropriate method of service

- Served personally upon the defendant. Place where served: _____
- Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein.
Name of person with whom the summons and complaint were left: _____
- Returned unexecuted: _____
- Other (specify): _____

STATEMENT OF SERVICE FEES

TRAVEL	SERVICES	TOTAL
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DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on _____

Date

Signature of Server

Address of Server

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

File #240613-06/rag

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----x
PAUL JOHNSON,

Plaintiff,

-against-

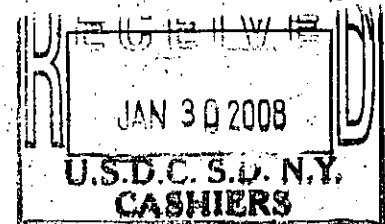
ELI LILLY AND COMPANY,

Defendant.
-----x

COMPLAINT

Plaintiff Demands
Trial by Jury

08 CV 0987



Plaintiff, by attorneys, FINKELSTEIN & PARTNERS, LLP, as and for the Verified
Complaint herein allege upon information and belief the following:

STATEMENT OF THE CASE

1. This is an action to recover damages for personal injuries sustained by Plaintiff, PAUL JOHNSON, as the direct and proximate result of the wrongful conduct of Defendant, ELI LILLY AND COMPANY, in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the prescription drug Zyprexa.

PARTIES AND JURISDICTION

2. Jurisdiction exists as against Defendant, ELI LILLY AND COMPANY, pursuant to:

(a) 28 U.S.C. Section 1332, in that Plaintiff, PAUL JOHNSON, was and still is a citizen and resident of the State of New York, and Defendant, ELI LILLY AND COMPANY, is incorporated in business in the State of Indiana and maintains its principal place of business in

the State of Indiana, and the amount in controversy exceeds the sum of \$75,000.00 exclusive of interest and costs.

(b) 28 U.S.C. Section 1391, in that jurisdiction is founded only on diversity of citizenship, and the Judicial District of the Southern District of New York is a judicial district in which a substantial part of the events or omissions giving rise to Plaintiff's claims occurred.

3. That at all times hereinafter mentioned, upon information and belief, Defendant was and still is a foreign corporation organized under the laws of the State of Indiana.

4. That at all times hereinafter mentioned, upon information and belief, Defendant was and still is a foreign corporation authorized to do business in the State of New York.

5. That at all times hereinafter mentioned, upon information and belief, Defendant was and still is a business entity actually doing business in the State of New York.

6. That at all times hereinafter mentioned, upon information and belief, Defendant presently markets and sells the drug Zyprexa.

7. That on a date prior to February 1, 2005, Defendant marketed and sold the drug Zyprexa.

8. That at all times hereinafter mentioned, upon information and belief, Defendant is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Zyprexa, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

9. That at all times hereinafter mentioned, upon information and belief, Defendant committed a tortious act inside the State of New York, which caused injury to Plaintiff inside the State of New York.

10. That at all times hereinafter mentioned, upon information and belief, Defendant committed a tortious act outside the State of New York, which caused injury to Plaintiff inside the State of New York.

11. That at all times hereinafter mentioned, upon information and belief, Defendant regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

12. That at all times hereinafter mentioned, upon information and belief, Defendant expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

BACKGROUND

NATURE OF THE CASE

13. Defendant designed, researched, manufactured, promoted, marketed, sold and distributed the drugs Zyprexa and Zyprexa Zydis, also known as Olanzapine, (hereinafter individually and collectively referred to as "Zyprexa"), for the treatment of schizophrenia and bipolar mania.

14. As a result of the defective nature of Zyprexa, those persons who used and were exposed to Zyprexa, including Plaintiff, have suffered and/or may continue to suffer severe and permanent personal injuries, including an increased risk of developing diabetic mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent health consequences.

15. Defendant concealed its knowledge of Zyprexa's defects from Plaintiff and Plaintiff's psychiatrists, physicians, hospitals and pharmacists.

16. Defendant failed to adequately conduct testing and/or research on Zyprexa, prior to marketing, manufacturing, distributing and/or selling said drug.

17. Defendant failed to adequately conduct post-marketing surveillance and/or testing of its drug Zyprexa subsequent to its marketing, manufacturing, distribution, and/or selling of said drug.

18. Defendant under-reported, underestimated and downplayed the serious and dangerous side effects of Zyprexa.

19. Consequently, Plaintiff seeks compensatory damages as a result of Plaintiff's exposure to Zyprexa, which has caused and will continue to cause Plaintiff to suffer physical pain, mental anguish, medical and other related personal injuries and/or expenses.

FACTUAL ALLEGATIONS

20. At all relevant times, Defendant was in the business of, and did create, design, manufacture, test, formulate, advertise, market, promote, sell, purchase and/or distribute Zyprexa.

21. The Food & Drug Administration ("FDA") approved Zyprexa for use for the treatment of schizophrenia with a target dosage of 10 mg/d in 1996.

22. In 2001, Zyprexa updated its labeling to include a newly approved indication for the short-term treatment of acute manic episodes associated with Bipolar I Disorder with recommended doses of 10-20 mg/d in 2000.

23. Zyprexa is Defendant's top-selling drug. Despite its limited approval for marketing, in eight years, Zyprexa has become the third-best selling drug in the world. Zyprexa's worldwide sales in 1997, its first full year on the market were \$500 million.

According to Defendant's Form 10K, 2004 worldwide Zyprexa sales exceeded \$4.4 billion, which made Zyprexa Defendant's top selling drug by over \$3.2 billion.

24. Zyprexa is an "atypical" antipsychotic medication.

25. Zyprexa purportedly works to reduce symptoms of schizophrenia by blocking various serotonin and dopamine receptors.

26. Patients, including Plaintiff, who are prescribed Zyprexa, have available numerous alternatives, including but not limited to other "atypical" antipsychotic medications, such as Risperdal, Quetiapine, Ziprasidone, and Clozapine, as well as other, older, antipsychotic medications, including but not limited to Haldol.

27. In recent studies in Europe and Japan, many cases have been discovered in which patients suffered severe and permanent personal injuries, including changes in the patient's blood glucose, due to the use of Defendant's Zyprexa.

28. In July 2002, a study at Duke University further showed a connection between Zyprexa and diabetes. The study documented nearly 300 cases of diabetes in patients using Zyprexa.

29. The British Medical Control Agency has warned about the risk of diabetes for patients prescribed Zyprexa.

30. The Japanese Health & Welfare Ministry has warned about the risk of diabetes for patients prescribed Zyprexa.

31. Defendant has not warned about the risk of diabetes for patients prescribed Zyprexa, or other risks associated with use of Zyprexa and for which patients have suffered.

32. Defendant's own pre-clinical studies regarding Zyprexa and medical literature related to antipsychotic drugs dating to the 1950's demonstrate that Zyprexa and other

antipsychotic drugs cause weight gain and hyperglycemia. Further, immediately after Zyprexa's release, Defendant became aware of large numbers of adverse event reports ("AERs") on file with the FDA's Medwatch database involving diabetes-related illnesses associated with the use of Zyprexa. Specifically, there were 200 AERs after two years of marketing, 400 AERs after three years, and nearly 600 diabetes-related AERs in Zyprexa's fourth year of marketing, all of which were reported to the FDA and known to Defendant. Additional evidence that Defendant knew of Zyprexa's propensity to cause diabetes and yet failed to adequately warn physicians and patients to the fact is that in April 2002, nearly a year and a half before Defendant first warned of the risk of diabetes in the United States, Defendant changed its labeling in the United Kingdom and Japan to include warnings regarding the association between the use of Zyprexa and diabetes-related injuries. Defendant has been required to revise the labeling of Zyprexa seventeen times since its introduction to the market. Prior to Plaintiff's ingestion of Zyprexa, there was no warning on Zyprexa's label or product information in the United States about the danger of developing diabetes.

33. On September 11, 2003, the FDA informed all manufacturers of atypical antipsychotic drugs, including Defendant, that due to an increasing prevalence of diabetes-related illnesses associated with this class of drugs, all labeling must bear the following language in the Warnings section:

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hypersomnolent coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiologic studies suggest an increased risk of treatment emergent hyperglycemia-related adverse events in patients treated with atypical

antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

34. Despite the FDA's mandate that Defendant immediately warn of the dangers described above, Defendant waited an additional six (6) months, until March 1, 2004, to send prescribing physicians a "Dear Doctor Letter" advising of the new warnings. Further, the foregoing warning did not appear in the Physicians Desk Reference until the 2005 edition.

35. In March 2004, the U.S. Attorney for the Eastern District of Pennsylvania commenced an investigation into Defendant's marketing practices concerning Zyprexa. Defendant has also recently received a grand jury subpoena from the Office of Consumer Litigation, Department of Justice, concerning the marketing and promotional practices with respect to a different Eli Lilly drug.

36. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the United States Government.

37. Upon information and belief, Defendant promoted Zyprexa by employing the illegal direct solicitation of physicians for off-label uses, and making false statements to physicians and pharmacists concerning the efficacy and safety of Zyprexa for off-label uses. As a result of Defendant's illegal scheme, Plaintiff was prescribed Zyprexa for an unnecessary and off-label use.

38. There is no valid scientific evidence to support the contention that Zyprexa is safe and effective for treatment of any off-label use. There is not valid scientific evidence concerning the therapeutic equivalence of Zyprexa for any off-label use.

39. Defendant sold or aided and abetted in the sale of Zyprexa which was and is defective and unreasonably dangerous. At all pertinent times, Defendant knew or should have known that Zyprexa was and is hazardous to human health.

40. Defendant, through its funding and control of certain studies concerning the effects of Zyprexa on human health, their control over trade publications, promoting, marketing, and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or misrepresentation of the true relationship between Zyprexa and various diseases, all to the detriment of the public health, safety and welfare and thereby causing harm.

41. Specifically, and in addition to the allegations above, Defendant knew of the hazards associated with Zyprexa; affirmatively and actively concealed information which clearly demonstrated the dangers of Zyprexa, and affirmatively misled the public and prescribing physicians with regard to the material and clear risks of Zyprexa; Defendant did so with the intent that prescribing physicians would continue to prescribe Zyprexa; Defendant well knew that prescribing physicians would not be in a position to know the true risks of Zyprexa; and

Defendant knew that prescribing physicians would rely upon the misleading information that Defendant promulgated.

42. At all pertinent times, Defendant purposefully and intentionally engaged in these activities, and continues to do so, knowing full well that when the general public, including Plaintiff, used Zyprexa as Defendant intended, users such as Plaintiff would be substantially certain to suffer disease, injury and sickness.

43. The statements, representations and promotional schemes publicized by Defendant were deceptive, false, incomplete, misleading and untrue. Defendant knew, or should have known, that its statements, representations and advertisements were deceptive, false, incomplete, misleading and untrue at the time of making such statements. Defendant had an economic interest in making such statements. Neither Plaintiff nor the physicians who prescribed Zyprexa had knowledge of the falsity or untruth of Defendant's statements, representations and advertisements when prescriptions for Zyprexa were written; moreover, Plaintiff and his physician had a right to rely on Defendant's statements and advertisements. Each of the statements, representations and advertisements were material to Plaintiff's purchase of Zyprexa in that Plaintiff would not have purchased Zyprexa if he had known that Defendant's statements, representations and advertisements were deceptive, false, incomplete, misleading and untrue.

44. Plaintiff had a right to rely upon the representations of Defendant and was directly and proximately injured by such reliance as heretofore described.

45. Had Plaintiff been adequately warned of the potential life-threatening side effects, Plaintiff could have chosen to request other prescription medications and avoided Zyprexa's potential life-threatening side effects.

46. Defendant failed to appropriately warn Plaintiff, his psychiatrists, physicians, hospitals, and pharmacists, of the dangerous risk of developing diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis and diabetic coma, as well as other severe and permanent health consequences from the use of Zyprexa.

47. Defendant knew, or should have known, of the above-mentioned risks based upon the state of knowledge of Zyprexa as it existed at that time, and upon generally accepted medical and research standards and principles.

48. Defendant made certain claims which were distributed and circulated to the medical and psychiatric professions and to the general public stating that Zyprexa was a safe and efficacious product for the treatment of schizophrenia and bipolar mania.

49. Defendant was careless and negligent in the manufacturing, testing, designing, selling, distributing, merchandising, advertising, promoting, compounding, packaging, fabricating, analyzing, marketing, and recommending Zyprexa and Defendant's conduct constituted a wanton, willful and reckless disregard for the safety of the public and Plaintiff in particular.

50. Plaintiff used the drug Zyprexa from approximately May 2003 through May 2005.

51. By reason of the foregoing, Plaintiff has developed, or is at an extremely high risk of developing diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent health afflictions.

52. Plaintiff has endured and continues to suffer from mental anguish and psychological trauma of living with the knowledge that he has, or may contract diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent health consequences as a result of Defendant's aforementioned conduct.

53. By reason of the foregoing, Plaintiff has been severely and permanently injured and will require constant and continuous medical monitoring and treatment.

**AS AND FOR A FIRST CAUSE OF
ACTION AGAINST THE DEFENDANT**

54. Plaintiff repeats, reiterates and realleges each and every allegation previously set forth herein.

55. Defendant has a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distribution of Zyprexa into the stream of commerce, including a duty to assure that the product did not cause users to suffer from unreasonable, dangerous side effects.

56. Defendant failed to exercise ordinary care in the design, researching, manufacturing, marketing, supplying, promoting, packaging, selling, testing, quality assurance, quality control, and/or distribution of Zyprexa into interstate commerce in that Defendant knew or should have known that using Zyprexa created a high risk of unreasonable, dangerous side effects, including but not limited to diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent health consequences.

57. The negligence of Defendant, its agents, servants and/or employees, including but was not limited to the following acts and/or omissions:

- (a) Manufacturing, producing, promoting, formulating, creating, and/or designing Zyprexa without adequately testing it;
- (b) Manufacturing, producing, promoting, formulating, creating, and/or designing Zyprexa without testing it;
- (c) Not conducting sufficient testing programs to determine whether or not the aforesaid drug was safe for use; in that Defendant knew or should have known, that said drug was unsafe and unfit for use by reason of the dangerous effects, contraindications and inherent dangers to its users;

- (d) Selling Zyprexa without making proper and sufficient tests to determine that dangers and/or contraindications thereof;
- (e) Negligently failing to adequately and correctly warn the public and the medical, psychiatric and healthcare profession of the dangers, contraindications, and/or side effects of Zyprexa;
- (f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with Zyprexa;
- (g) Negligently advertising and recommending the use of Zyprexa without sufficient knowledge as to its dangerous propensities;
- (h) Negligently representing that said drug was safe for use for its intended purpose, when, in fact, it was unsafe;
- (i) Improperly obtaining the approval of the FDA to market the drug after misrepresenting the risks of the drug to the FDA, in knowing this was a substance which caused injury to its users;
- (j) Failing to do appropriate post-market testing of Zyprexa; and
- (k) Failing to appropriate post-market surveillance of Zyprexa.

58. Defendant under-reported, underestimated and downplayed the serious and dangerous side effects of Zyprexa:

59. Defendant was negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marking and sale of Zyprexa in that Defendant:

- (a) Failed to use due care in designing and manufacturing Zyprexa so as to avoid the aforementioned risks to individuals when Zyprexa was used for the treatment of schizophrenia, bipolar mania, and/or other off-label uses;
- (b) Failed to accompany their product with proper warnings regarding possible adverse side effects associated with the use of Zyprexa;
- (c) Failed to warn Plaintiff of the severity and duration of such adverse side effects, as the warnings given did not accurately reflect the symptoms, and/or severity of the side effects;

- (d) Failed to conduct adequate testing, including pre-clinical and clinical testing and/or post-marketing surveillance to determine the safety of Zyprexa for use in schizophrenia, bipolar mania, and/or other off-label use for which Zyprexa was and/or still is used;
- (e) Failed to warn Plaintiff prior to actively encouraging the sale of Zyprexa, either directly or indirectly, orally or in writing, about the need for comprehensive, regular medical monitoring to ensure early discovery of potentially serious side effects;
- (f) Was otherwise careless or negligent.

60. Despite the fact that Defendant knew or should have known that Zyprexa caused unreasonably dangerous side effects, Defendant continued and is currently continuing to market, manufacture, distribute and/or sell Zyprexa to consumers, including but not limited to Plaintiff.

61. Defendant knew or should have known that consumers such as Plaintiff would foreseeable suffer injury as a result of Defendant's failure to exercise ordinary care.

62. Defendant's negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered and will continue to suffer.

63. As a result of the foregoing acts and omissions, Plaintiff was, and still is caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, loss of earnings, medical and psychiatric expenses, and other serious injuries which are permanent and lasting in nature.

64. As a result of the foregoing acts and omissions, Plaintiff required and will require health care and services, and did incur medical, psychiatric, health, incidental and related expenses. Plaintiff will in the future be required to obtain further medical and/or hospital care, attention and services.

65. As a result of the foregoing acts and omissions, Plaintiff seeks actual, compensatory and punitive damages from Defendant as alleged herein.

**AS AND FOR A SECOND CAUSE OF
ACTION AGAINST THE DEFENDANT**

66. Plaintiff repeats, reiterates and realleges each and every allegation previously set forth herein:

67. At all times herein mentioned, Defendant manufactured, compounded, distributed, recommended, supplied, merchandized, advertised, promoted and/or sold, the aforesaid Zyprexa as hereinabove described, and Plaintiff used said product.

68. Zyprexa was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by Defendant.

69. At those times, the drug product Zyprexa, was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, Plaintiff.

70. The Zyprexa manufactured and/or supplied by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer and/or supplier, the foreseeable risks exceeded the benefits associated with the design or formulation.

71. The Zyprexa manufactured and/or supplied by Defendant was defective in design and/or formulation, in that, when it left the hands of the manufacturer and/or supplier, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer, including Plaintiff, would expect.

72. At all times herein mentioned, the said drug product Zyprexa was in a defective condition and unsafe, and Defendant knew or had reason to know that said product was defective and unsafe, especially when used in the form and/or manner as provided by Defendant.

73. Defendant knew, or should have known that at all times herein mentioned its Zyprexa was in a defective condition, inherently dangerous and unsafe.

74. At the time of Plaintiff's use of Zyprexa, the Zyprexa was being used for the purpose and in a manner normally intended; recommended; promoted and/or marketed by Defendant.

75. Defendant, with this knowledge, voluntarily designed Zyprexa in a dangerous condition for consumption by the public, and in particular, Plaintiff.

76. Defendant had a duty to create and/or sell a product that was not unreasonably dangerous for its normal, intended use.

77. Defendant created and/or sold a product unreasonably dangerous for its normal, intended use.

78. Defendant designed, manufactured, and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff, and Defendant is therefore strictly liable for the injuries sustained by Plaintiff.

79. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

80. The Zyprexa manufactured and/or supplied by Defendant was defective due to inadequate warnings or instructions because the manufacturer knew or should have known that the product created a high risk of developing diabetes mellitus, pancreatitis, hyperglycemia,

diabetic ketoacidosis and diabetic coma, as well as other severe and permanent health consequences, and Defendant failed to adequately warn of said risks.

81. The Zyprexa manufactured and/or supplied by Defendant was defective due to inadequate warnings an/or inadequate testing.

82. The Zyprexa manufactured and/or supplied by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after the manufacturer knew or should have known of the risks of developing diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis and/or diabetic coma, and other serious health risks from Zyprexa, it failed to provide adequate warnings to users, consumers, and/or prescribing physicians, psychiatrists, pharmacies and hospitals of the product, and continued to promote the product.

83. By reason of the foregoing, Defendant has become strictly liable in tort to Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, Zyprexa.

84. Defendant's defective design, manufacturing defect, and inadequate warnings of Zyprexa were acts that amount to willful, wanton, and/or reckless conduct by Defendant.

85. Said defects in Defendant's Zyprexa were a substantial factor in causing Plaintiff's injuries.

86. As a result of the foregoing acts and omissions, Plaintiff was, and still is caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, loss of earnings, medical and psychiatric expenses, and other serious injuries which are permanent and lasting in nature.

87. As a result of the foregoing acts and omissions, Plaintiff required and will require health care and services, and did incur medical, psychiatric, health, incidental and related expenses. Plaintiff will in the future be required to obtain further medical and/or hospital care, attention and services.

88. As a result of the foregoing acts and omissions, Plaintiff seeks actual, compensatory and punitive damages from Defendant as alleged herein.

**AS AND FOR A THIRD CAUSE OF
ACTION AGAINST THE DEFENDANT**

89. Plaintiff repeats, reiterates and realleges each and every allegation previously set forth herein.

90. Defendant expressly warranted that Zyprexa was safe and well accepted by users.

91. Plaintiff relied on the express warranties of Defendant.

92. Members of the medical community, including physicians, psychiatrists, and other healthcare professionals, relied upon the representations and warranties of Defendant for use of said drug Zyprexa in prescribing, recommending and or dispensing this product.

93. Defendant breached the aforesaid express warranties, as its product Zyprexa was defective, as is, and has been, set forth herein.

94. Defendant expressly represented to the users and their physicians, psychiatrists, and healthcare providers that said drug Zyprexa was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

95. Defendant knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that said drug Zyprexa was not safe and fit for the use intended, and, in fact, produces serious injuries to the user.

96. Zyprexa does not conform to these express representations because Zyprexa is not safe and has numerous serious side effects.

97. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

98. As a result of the foregoing acts and omissions, Plaintiff was, and still is caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, loss of earnings, medical and psychiatric expenses, and other serious injuries which are permanent and lasting in nature.

99. As a result of the foregoing acts and omissions, Plaintiff required and will require health care and services, and did incur medical, psychiatric, health, incidental and related expenses. Plaintiff will in the future be required to obtain further medical and/or hospital care, attention and services.

100. As a result of the foregoing acts and omissions, Plaintiff seeks actual, compensatory and punitive damages from Defendant as alleged herein.

**AS AND FOR A FOURTH CAUSE OF
ACTION AGAINST THE DEFENDANT**

101. Plaintiff repeats, reiterates and realleges each and every allegation previously set forth herein.

102. At all times herein mentioned, Defendant manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold Zyprexa.

103. At all times Defendant marketed, sold and distributed Zyprexa for use by Plaintiff, Defendant knew of the use for which Zyprexa was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

104. Defendant manufactured, compounded, packages, distributed, recommended, merchandised, advertised, promoted, supplied and sold the aforesaid product, and prior to the time it was prescribed to Plaintiff, Defendant impliedly warranted to Plaintiff that the product was of merchantable quality and safe for the use for which is was intended.

105. The product was unsafe for its intended use, and it was not of merchantable quality as warranted by Defendant in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. The aforesaid product was unaccompanied by warnings of its dangerous propensities that either were known for reasonably scientifically knowable at the time of distribution. The aforesaid product did cause Plaintiff to sustain the injuries as herein alleged.

106. Defendant impliedly represented and warranted to Plaintiff that the Zyprexa it was supplying to Plaintiff was safe and fit for ordinary use.

107. Defendant impliedly represented and warranted to the users and their physicians, psychiatrists, and healthcare providers that Zyprexa was safe and of merchantable quality, and fit for the ordinary purpose for which said product was to be used.

108. Said representation and warranties aforementioned were false, misleading and inaccurate in that said drug product Zyprexa, and unsafe, unreasonable, dangerous, improper, not of merchantable quality and defective.

109. Plaintiff and members of the medical community did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

110. Plaintiff and Plaintiff's physicians, psychiatrists, and pharmacists reasonably relied upon the skill and judgment of Defendant as to whether Zyprexa was of merchantable quality and safe and fit for its intended use.

111. Zyprexa products were injected into the stream of commerce by Defendant in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

112. Defendant breached the aforesaid implied warranties, as its product Zyprexa was not fit for its intended purpose and use.

113. As a result of the foregoing acts and omissions, Plaintiff was, and still is caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, loss of earnings, medical and psychiatric expenses, and other serious injuries which are permanent and lasting in nature.

114. As a result of the foregoing acts and omissions, Plaintiff required and will require health care and services, and did incur medical, psychiatric, health, incidental and related expenses. Plaintiff will in the future be required to obtain further medical and/or hospital care, attention and services.

115. When Plaintiff was made aware that his injuries were a result of the aforesaid product, notice was duly given to Defendant of the breach of warranty by way of this Complaint.

116. As a result of the foregoing acts and omissions, Plaintiff seeks actual, compensatory and punitive damages from Defendant as alleged herein.

**AS AND FOR A FIFTH CAUSE OF
ACTION AGAINST THE DEFENDANT**

117. Plaintiff repeats, reiterates and realleges each and every allegation previously set forth herein.

118. Defendant falsely and fraudulently misrepresented to the medical and psychiatric community, and to Plaintiff and the public in general, that said product Zyprexa had been tested and found to be safe and effective for the treatment of schizophrenia and bipolar mania.

119. The representations made by Defendant were, in fact, false.

120. When said representations were made by Defendant, it knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

121. These representations were made by Defendant with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and psychiatric community in particular, and with the intent of inducing Plaintiff, the public in general, and the medical and psychiatric community in particular, to recommend, dispense and purchase said product Zyprexa for use in treating schizophrenia and bipolar mania, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety and welfare of Plaintiff.

122. At the time the aforesaid representations were made by Defendant, and at the time Plaintiff used Zyprexa, Plaintiff was unaware of the falsity and said representations and reasonably believed them to be true.

123. In reliance upon said representations, Plaintiff was induced to and did use Zyprexa, thereby sustaining severe and permanent personal injuries, and/or is now an increased risk of sustaining severe and permanent personal injuries in the future.

124. Defendant knew and was aware or should have known that Zyprexa had not been sufficiently tested, was defective in nature, and that it lacked adequate warnings.

125. Defendant knew or should have known that Zyprexa had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous.

126. Defendant brought Zyprexa to the market, and acted fraudulently, wantonly, and maliciously to the detriment of Plaintiff.

127. As a result of the foregoing acts and omissions, Plaintiff was, and still is caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, loss of earnings, medical and psychiatric expenses, and other serious injuries which are permanent and lasting in nature.

128. As a result of the foregoing acts and omissions, Plaintiff required and will require health care and services, and did incur medical, psychiatric, health, incidental and related expenses. Plaintiff will in the future be required to obtain further medical and/or hospital care, attention and services.

129. As a result of the foregoing acts and omissions, Plaintiff seeks actual, compensatory and punitive damages from Defendant as alleged herein.

**AS AND FOR A SIXTH CAUSE OF
ACTION AGAINST THE DEFENDANT**

130. Plaintiff repeats, reiterates and realleges each and every allegation previously set forth herein.

131. At all times during the course of dealing between Defendant and Plaintiff, Defendant misrepresented that Zyprexa was safe for its intended use.

132. Defendant knew or was reckless in not knowing that its representations were false.

133. In representations to Plaintiff, Defendant fraudulently concealed and intentionally omitted the following material information:

- (a) That Zyprexa was not safe for use in treating schizophrenia or bipolar mania;
- (b) That Defendant was aware of Zyprexa's dangers;
- (c) That Zyprexa was defective, and that it caused dangerous side effects, including but not limited to developing diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent health consequences; and
- (d) That patients needed to be regularly monitored while taking Zyprexa.

134. Moreover, Defendant made material representations that were false and that were either known false when made or were asserted without knowledge of their truth. Defendant had in its possession adverse drug event reports, drug studies and other documentation about Zyprexa and yet made the following representations:

- (a) That Zyprexa was not safe for use in treating schizophrenia or bipolar mania;
- (b) Misrepresentations regarding the frequency of Zyprexa-related adverse event reports or occurrences in the Zyprexa label, package insert or PDR label;

- (c) Misrepresentations as to the existence, occurrence and frequency of occurrences, severity and extent of the overall risks of Zyprexa;
- (d) Misrepresentations as to the number of adverse events and deaths reported with the use of Zyprexa;
- (e) Misrepresentations as to the efficacy of Zyprexa; and
- (f) Misrepresentations regarding the nature, seriousness, and severity of adverse events reported with the use of Zyprexa.

135. Defendant was under a duty to disclose to Plaintiff and his physicians, psychiatrists, hospitals, and pharmacists, the defective nature of Zyprexa, and/or the risks and dangers associated with Zyprexa.

136. Defendant had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence caused damage to persons who used Zyprexa, including Plaintiff.

137. Defendant's concealment and omissions of material facts concerning, inter alia, the safety of Zyprexa, were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and his physicians, psychiatrists, hospitals and pharmacists into reliance, continued use of Zyprexa, and actions thereon, and to cause them to purchase Zyprexa and/or use the product.

138. Defendant knew that Plaintiff and Plaintiff's physicians, psychiatrists, hospitals, and pharmacists had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding Zyprexa.

139. Plaintiff, as well as Plaintiff's doctors, psychiatrists, health care providers, and/or hospitals reasonably relied on Defendant's concealment and/or omissions of fact.

140. As a result of the foregoing acts and omissions, Plaintiff was, and still is caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, diabetes mellitus, pancreatitis, hyperglycemia, diabetic

ketoacidosis, and diabetic coma, loss of earnings, medical and psychiatric expenses, and other serious injuries which are permanent and lasting in nature.

141. Defendant is estopped from asserting a statute of limitations defense because Defendant fraudulently concealed from Plaintiff the nature of Plaintiff's injury and the connection between the injury and Zyprexa.

142. As a result of the foregoing acts and omissions, Plaintiff required and will require health care and services; and did incur medical, psychiatric, health, incidental and related expenses. Plaintiff will in the future be required to obtain further medical and/or hospital care, attention and services.

143. As a result of the foregoing acts and omissions, Plaintiff seeks actual, compensatory and punitive damages from Defendant as alleged herein.

**AS AND FOR A SEVENTH CAUSE OF
ACTION AGAINST THE DEFENDANT**

144. Plaintiff repeats, reiterates and realleges each and every allegation previously set forth herein.

145. Defendant had and continues to have a duty to represent to the medical and psychiatric community, to Plaintiff, and to the public in general, that said product Zyprexa had been tested and found to be safe and effective for use in treating schizophrenia and bipolar mania.

146. Defendant had, and continues to have, a duty to the medical and psychiatric community, to Plaintiff, and to the public in general to market, manufacturer, distribute, and/or sell its drug Zyprexa with appropriate and/or adequate information and/or warnings.

147. The representations made by Defendant were, in fact, false.

148. Defendant failed to exercise ordinary care in the representation of Zyprexa while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendant negligently misrepresented Zyprexa's high risk of unreasonable, dangerous side effects.

149. Defendant breached its duty to represent Zyprexa's serious side effects to the medical and psychiatric community, to Plaintiff, and to the public in general.

150. As a result of the negligent misrepresentations of Defendant set forth hereinabove, Defendant knew and was aware or should have known and been aware that the drug had been insufficiently tested, that it had not been tested, that it lacked adequate warnings, and/or that it created a high risk of unreasonable, dangerous side effects, including but not limited to developing diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent health consequences, loss of earnings, medical and psychiatric expenses and other serious injuries which are permanent and lasting in nature.

151. As a result of the foregoing acts and omissions, Plaintiff was, and still is caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life; diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, loss of earnings; medical and psychiatric expenses, and other serious injuries which are permanent and lasting in nature.

152. As a result of the foregoing acts and omissions, Plaintiff required and will require health care and services, and did incur medical, psychiatric, health, incidental and related expenses. Plaintiff will in the future be required to obtain further medical and/or hospital care, attention and services.

153. As a result of the foregoing acts and omissions, Plaintiff seeks actual, compensatory and punitive damages from Defendant as alleged herein.

**AS AND FOR A EIGHTH CAUSE OF
ACTION AGAINST THE DEFENDANT**

154. Plaintiff repeats, reiterates and realleges each and every allegation previously set forth herein.

155. Defendant acted, intentionally and willfully, used and employed deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts with intent that physicians and medical providers rely upon such concealment, suppression and omission, and for the purpose of influencing and inducing physicians and medical providers to prescribe Zyprexa, at excessively high dosages, for unapproved "off-label" uses, including treatment for depressive disorder with psychotic symptoms, to patients/consumers such as Plaintiff, and causing such patients/consumers to purchase, acquire and use Zyprexa, at high dosages, for unapproved "off-label" uses, including treatment for depressive disorder with psychotic symptoms, as prescribed by their physicians and medical providers, in connection with the sale and advertisement of the drug Zyprexa, in violation of General Business Law §§ 349 and 350.

156. By reason of Defendant's acts, uses and employment of deception, unfair and deceptive acts and practices, fraud, false promises, misrepresentations, concealment, suppression and omission of material facts, reasonable patients/consumers acting reasonably, such as Plaintiff, were caused to suffer severe and permanent personal injuries, physical pain and mental anguish, including diminished enjoyment of life, diabetes mellitus, pancreatitis,

hyperglycemia, diabetic ketoacidosis, and diabetic coma, loss of earnings, medical and psychiatric expenses, and other serious injuries which are permanent and lasting in nature.

157. By reason of the facts and premises aforesaid, Plaintiff was damaged in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdictional limits of this matter, and in addition, Plaintiff seeks an increase of the award of actual damages to an amount not to exceed three times the actual damages up to one thousand dollars, and reasonable attorney's fees, as may be found by the Court upon the trial of this Action.

WHEREFORE, Plaintiff demands judgment against the Defendant as follows:

(1) The sum of \$100,000,000.00 on the First Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(2) The sum of \$100,000,000.00 on the Second Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(3) The sum of \$100,000,000.00 on the Third Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(4) The sum of \$100,000,000.00 on the Fourth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(5) The sum of \$100,000,000.00 on the Fifth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

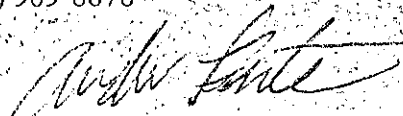
(6) The sum of \$100,000,000.00 on the Sixth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon trial of this Action;

(7) The sum of \$100,000,000.00 on the Seventh Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon trial of this Action; and

(8) A sum in the amount of actual damages on the Eighth Cause of Action and further, Plaintiff seeks an increase of the award of actual damages to an amount not to exceed three times the actual damages up to one thousand dollars, together with interest, costs and disbursements of this Action.

Dated: Newburgh, NY
January 29, 2008

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By: 
ANDREW G. FINKELSTEIN, ESQ.

TO: ELI LILLY AND COMPANY
Defendant
c/o Secretary of State
41 State Street
Albany, New York 12231